

# The Food and Drug Administration: An Overview

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Department of Health  
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# The FDA Mission

- To Protect the public health, as directed by the Food, Drug and Cosmetic Act.
- To Administer the statutory framework for providing new and better products.

# Drug Development and Investigational New Drug Applications (IND)

What is an IND ?

Purpose of an IND

Who needs an IND ?

What are the IND exemptions ?

Where do I get more information?

# What is an IND?

- **NOT an application for Marketing Approval**
- **Request for exemption from federal statute that prohibits an unapproved drug from being shipped in interstate commerce.**

# Purpose of an IND?

- Provide data showing that it is reasonable to begin tests of a new drug in humans.
  - based on preclinical data
- Allow for shipment of drug across state lines

# Who needs and IND ?

- Clinical study of an unapproved product
- Clinical study –
  - investigational use of approved product (experiment administering drug to human)
  - clinical trial
  - UNLESS receive an Exemption

# What are the IND exemptions ?

**Must meet all of the following:**

- Not intended to support a change in indication
- No increase in risk (route of administration, dose, subject population)
- Not intended to support changes in advertising

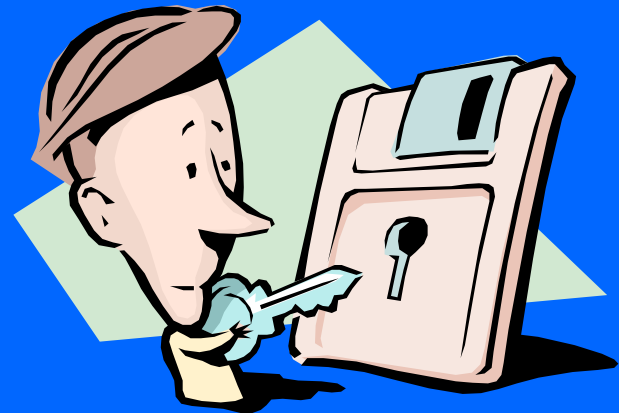
# What are the IND exemptions ?

*(con't)*

- In compliance with IRB and Informed Consent
- In compliance with requirements re: promotion and sale of drugs (21 CFR 312.7)
- Not seeking exception from informed consent requirements for emergency research



For more information .....





# Drug Applications

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## APPLICATION PROCESS:

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### Investigational New Drug (IND) Application Process

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Commands for working with the selected items.

Frequently Asked Questions on Drug Development and Investigational New Drug Applications - Microsoft Internet Explorer

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Address http://www.fda.gov/cder/about/smallbiz/faq.htm#Investigational%20New%20Drug%20Process U.S. Food and Drug Administration • Center for Drug Evaluation and Research

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